



## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1301

[Docket No. DEA-1144]

RIN 1117-AB84

#### Controlled Substance Destruction Alternatives to Incineration

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Advance notice of proposed rulemaking.

**SUMMARY:** The Drug Enforcement Administration (DEA) is seeking information about destruction processes which may be used to render controlled substances to a non-retrievable state. DEA invites comment from stakeholders in the controlled substance disposal industry, as well as registrants engaged in the destruction and disposal of controlled substances in their possession or inventory, to the questions provided below.

**DATES:** Electronic comments must be submitted, and written comments must be postmarked, on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

**ADDRESSES:** To ensure proper handling of comments, please reference “RIN 1117-AB84/Docket No. DEA-1144” on all correspondence, including any attachments.

- *Electronic comments:* DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type comments directly into the comment field on the Web page or to attach a file containing comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number

for your comment generated by <http://www.regulations.gov>. Please be aware that submitted comments are not instantaneously available for public view on <http://www.regulations.gov>. If you have received a Comment Tracking Number, your comment has been successfully submitted, and there is no need to resubmit the same comment.

- *Paper comments:* Paper comments that duplicate the electronic submission are discouraged. Should you wish to mail a paper comment *in lieu of* submitting a comment electronically, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. Hand-delivered comments will not be accepted.

**FOR FURTHER INFORMATION CONTACT:** Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 776-3882.

## **SUPPLEMENTARY INFORMATION:**

### **Posting of Public Comments**

Please note that all comments received in response to this docket are considered part of the public record. The Drug Enforcement Administration (DEA) will make all comments available for public inspection online at <http://www.regulations.gov>. Such information includes personal or business identifiers (such as name, address, state or Federal identifiers, etc.) voluntarily submitted by the commenter. Generally, all information voluntarily submitted by the commenter, unless clearly marked as Confidential Information in the method described below, will be publicly posted. Comments may be submitted anonymously. The Freedom of Information Act applies to all comments received.

Commenters submitting comments which include personal identifying information (PII), confidential, or proprietary business information that the commenter does not want made publicly available should submit two copies of the comment. One copy must be marked “CONTAINS CONFIDENTIAL INFORMATION” and should clearly identify all PII or

business information the commenter does not want to be made publicly available, including any supplemental materials. DEA will review this copy, including the claimed PII and confidential business information, in its consideration of comments. The second copy should be marked “TO BE PUBLICLY POSTED” and must have all claimed confidential PII and business information already redacted. DEA will post only the redacted comment on <http://www.regulations.gov> for public inspection.

For easy reference, an electronic copy of this document and a plain language summary of this advanced notice of proposed rulemaking are available at <http://www.regulations.gov>.

### **Legal Authority**

DEA implements and enforces the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act, as amended.<sup>1</sup> DEA publishes the implementing regulations for these statutes in 21 CFR parts 1300 to end. These regulations are designed to ensure a sufficient supply of controlled substances for medical, scientific, and other legitimate purposes, and to deter the diversion of controlled substances for illicit purposes.

As mandated by the CSA, DEA establishes and maintains a closed system of control for the manufacturing, distribution, and dispensing of controlled substances. DEA’s regulations require that persons involved in the manufacture, distribution, research, dispensing, import, export, and disposal and destruction of controlled substances register with DEA (unless exempt), keep track of all stocks of controlled substances, and maintain records to account for all controlled substances received, distributed, or otherwise disposed of.

The CSA authorizes the DEA Administrator (Administrator), by delegation from the Attorney General,<sup>2</sup> to register an applicant to manufacture, distribute, or dispense controlled substances if such registration is determined to be consistent with the public interest.<sup>3</sup> The CSA

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<sup>1</sup> 21 U.S.C. 801-971.

<sup>2</sup> 21 U.S.C. 871; 28 CFR 0.100(b).

<sup>3</sup> 21 U.S.C. 823.

further authorizes the Administrator to promulgate regulations necessary and appropriate to execute the functions of the CSA relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances.<sup>4</sup>

## **Background**

On December 29, 2022, the President signed the Consolidated Appropriations Act, 2023.<sup>5</sup> In a related report issued by the United States Senate Appropriations Subcommittee on Commerce, Justice, Science, and Related Agencies, Congress encouraged DEA to engage in substantive conversations with industry stakeholders on alternatives to incineration that meet the non-retrievable standard.<sup>6</sup>

DEA regulations do not specify a particular required means for destruction of controlled substances. Instead, DEA regulations establish a result, by requiring registrants to dispose of controlled substances in their inventory using a method of destruction that permanently alters that controlled substance's physical or chemical condition or state through irreversible means, and thereby renders the controlled substance unavailable and unusable for all practical purposes.<sup>7</sup> The registrants are able to choose any method of destruction that satisfies this standard.

In an effort to identify chemical and technological methods of destruction of controlled substances other than incineration which may meet the disposal requirements of DEA registrants, and to promote the public exchange of technology and process development information, DEA invites comment to the questions provided in this advanced notice of proposed rulemaking (ANPRM).

## **History**

Congress amended the CSA to include the Secure and Responsible Drug Disposal Act of 2010 (SRDDA).<sup>8</sup> In 2014, DEA published a final rule entitled, "Disposal of Controlled

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<sup>4</sup> 21 U.S.C. 821.

<sup>5</sup> Pub. L. 117-328, 136 Stat. 4459.

<sup>6</sup> 117 Cong. Rec. S7921 (2022).

<sup>7</sup> 21 CFR 1300.05

<sup>8</sup> Pub. L. 111-273, 124 Stat. 2858.

Substances,” that implemented the provisions of the SRDDA and established parameters for registrants to safely and securely dispose of controlled substances that remain in their inventory.<sup>9</sup>

### **Non-retrievable Standard of Destruction**

In the final rule, DEA defined the term “non-retrievable,” and implemented it as the standard of destruction to be achieved by registrants that dispose of and destroy controlled substances from their inventory.<sup>10</sup> A controlled substance is considered non-retrievable when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue.<sup>11</sup> Specifically, the rule provides that the method of destruction used shall be consistent with the purpose of rendering all of the controlled substances to a non-retrievable state in order to prevent diversion and protect the public health and safety.<sup>12</sup> The rule also provides that controlled substances in a registrant’s inventory shall be destroyed in compliance with applicable Federal, State, tribal, and local laws and regulations.<sup>13</sup>

DEA established the non-retrievable standard as the intended final result of a registrant’s disposal and destruction process in order to prevent the potential diversion of controlled substances into illegitimate channels. DEA believes the permanent and irreversible alteration of controlled substances is the cornerstone of the non-retrievable standard.<sup>14</sup>

In the final rule, in order to allow public and private entities to develop a variety of destruction methods that are secure, convenient, and responsible, DEA explained that it would not require a particular method of destruction, so long as the desired result of non-retrievability is achieved, and the method is consistent with preventing the diversion of controlled substances.<sup>15</sup>

### **Comments Requested**

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<sup>9</sup> 79 FR 53520 (Sept. 9, 2014).

<sup>10</sup> 21 CFR 1300.05; 21 CFR part 1317.

<sup>11</sup> 21 CFR 1300.05.

<sup>12</sup> 21 CFR 1317.90(c).

<sup>13</sup> 21 CFR 1317.90(a).

<sup>14</sup> 79 FR 53520, 53527.

<sup>15</sup> *Id.* at 53522.

DEA is aware that since the publication of the final rule in 2014, various chemical and technological processes have been developed and employed to render controlled substances non-retrievable. In the final rule, DEA stated its intent that methods of destruction should remain current with continuously changing technology.<sup>16</sup> DEA now invites stakeholders engaged in the destruction and disposal of controlled substances to respond to the questions provided in this ANPRM. If proprietary information is included in the response, please submit two copies, and clearly indicate which copy “Contains Confidential Information”, and which is the redacted version “To Be Publicly Posted” to ensure the correct information is posted on Regulations.gov. See Submitting Public Comments section, above.

#### **ANPRM QUESTIONS:**

Please identify destruction methods or technology currently being utilized or developed to render the controlled substances non-retrievable. For each method or technology identified, please include:

1. If known, the potential users of this method or technology.
2. A detailed description of the method of destruction or technical process utilized to achieve the non-retrievable standard. Does this method or technology involve incineration at any point to attain the non-retrievable standard?
3. The controlled substance(s) to which the method of destruction or technology to render the controlled substance(s) non-retrievable may be applicable.
4. If known, list any controlled substances that will not be rendered non-retrievable by this method.
5. The volume or throughput (per hour) required to render the controlled substance non-retrievable.
6. The registrant’s anticipated cost to execute, implement, or utilize the method of destruction or technology discussed above.
7. The analytical process utilized to evaluate the effectiveness of the method of destruction or technology. Provide the analytical results validating attainment of the non-retrievable standard.

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<sup>16</sup> *Id.* at 53548.

8. The characteristics or constituents of any by-products or waste generated through the process used to render the controlled substance non-retrievable. Provide the waste profile sheet or similar documentation showing analytical results of the by-products or waste generated.
9. The disposal process of the by-products or waste generated.
10. The Federal, state, or local regulatory requirements associated with the disposal process and/or disposal of the by-products or waste.

## **Regulatory Analysis**

This ANPRM was developed in accordance with the principles of Executive Order (E.O.) 12866, “Regulatory Planning and Review,” E.O. 13563, “Improving Regulation and Regulatory Review,” and E.O. 14094, “Modernizing Regulatory Review.” Since this action is an ANPRM, it does not create or propose to create any new requirements. Therefore, this regulatory action is not significant under section 3(f) of E.O. 12866.

Furthermore, the requirements of the Regulatory Flexibility Act do not apply to this action because, at this stage, it is an ANPRM and not a “rule” as defined in 5 U.S.C. 601. Following review of the comments received in response to this ANPRM, if DEA proceeds with a notice of proposed rulemaking regarding this matter, DEA will conduct all relevant analyses as required by statute or Executive Order.

## **Signing Authority**

This document of the Drug Enforcement Administration was signed on October 26, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

**Scott Brinks,**  
Federal Register Liaison Officer,  
Drug Enforcement Administration.

